Claim Rejections - 35 U.S.C. § 102

Claim 1 is rejected under 35 U.S.C. § 102(e) as being anticipated by Verdura, et al. (USPN 6,159,200). Reconsideration of claim 1, as amended herein, is respectfully requested.

Verdura, et al., discloses systems, methods, and instruments for minimally invasive surgery. More particularly, Verdura discloses a valved or self-sealing trocar or cannula for insertion into a body cavity such that a surgeon can insert his or her hand into the body cavity through a separate minimal incision, retrieve the instrument from the cannula, and then perform a surgical procedure with the instrument within the body cavity. Multiple instruments can be sequentially inserted into and removed from the body cavity as needed by the surgeon without requiring the surgeon to remove and insert his or her hand.

According to Verdura, et al., the outer surface of the cannula body can include helical protrusions for screwing the cannula into an opening into a body cavity (col. 3, ll. 23-25). Verdura, et al., therefore, discloses a hollow body which may be inserted into a body cavity of a surgical patient to assist the surgeon during a surgical procedure to perform the procedure while maintaining his or her hands within the body cavity. The system of Verdura, et al., is best used in hand-assisted minimally invasive surgical procedures within the abdomen or pelvis, although other sights within the body can be accessed.

The device reflected in Applicant's claim 1, in contrast, is an intravascular device for insertion into the bodily tissue and terminating in a vessel of medical patient. Unlike the device and system of Verdura, et al., Applicant's device is an indwelling intravascular device for drawing fluids from the vessel (e.g., vein or artery) or for introduction of medication into the vessel. In other words, Applicant's device, of claim 1, indwells in the bodily tissue of a medical patient as opposed to being

inserted only temporarily to assist a surgical procedure as is the device of Verdura, et al.

Moreover, claim 1 has been amended herein to clarify that the device of Applicant's claim 1 is an intravascular device comprising a body, including an interface and a cannula with the cannula extending into and terminating in the vessel while the interface remains in contact with the bodily tissue of the patient at the point of insertion.

The portion of the "body" of the Verdura, et al., device which is asserted in the Office action to include texture thereon employs an aggressive helical protrusion so as to allow the device to be essentially "screwed" into the bodily cavity of the patient during a surgical procedure such that the helical protrusions retain the device within the bodily cavity while expanding the surrounding tissue formed by a small incision. The device of Applicant's claim 1, on the other hand, includes a body having texture thereon, which when inserted into the bodily tissue of the medical patient, assists in restraining the body in place so as to allow fibroblast growth and adhesion onto and within the texture during the time in which the body is indwelling in the patient (which could be hours, days, weeks, or longer) to facilitate access into the patient's vessel for the withdrawal of fluids or the introduction of medication as necessary.

Verdura, et al., does not disclose an indwelling intravascular device including a "cannula extending into and terminating in the vessel" as recited in Applicant's claim 1. Therefore, claim 1, as amended, is not anticipated by Verdura, et al. The rejection under 35 U.S.C. § 102(e) is believed overcome. Allowance of claim 1 is respectfully requested.

In the Office action, claim 10 is rejected under 35 U.S.C. § 102(b) as being anticipated by McFarlane (USPN 4,046,144), or Feller, Jr., et al. (USPN 4,362,156). Reconsideration of claim 10, as amended, is respectfully requested.

Claim 10 has been amended herein to recite that a segment of the proximal portion for contact with the bodily tissue at the point of insertion wherein that segment is textured. Neither McFarlane or Feller, Jr., et al. disclose an intravenous stent which includes a texture on a segment of the proximal portion for contact with the bodily tissue at the point of insertion. Accordingly, the rejection of the claim 10, under 35 U.S.C. § 102(b) as being anticipated by McFarlane or Feller, Jr., et al., is overcome. Allowance of claim 10 is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 5-8 and 10-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Verdura, et al., in view of Fuller, Jr., et al., McFarlane, Muetterties, et al., and Steen, et al. Reconsideration of claims 5-8 and 10-18 is respectfully requested.

Claims 5-8 and 16-18 depend from claim 1. Applicant incorporates by reference herein the above remarks with regard Applicant's claim 1 as amended in light of the Verdura, et al. reference. Applicant's claim 1 is allowable at least for the reasons set forth therein. Since claims 5-8 depend from claim 1, claims 5-8 and 16-18 are, likewise, allowable at least for the reasons set forth above with regard to claim 1. Reconsideration and allowance of claims 5-8 and 16-18 is respectfully requested.

Claims 11-15 depend from claim 10. Claim 10 has been amended herein to recite that the segment of the distal portion of the introducer for contact with bodily tissue at the point of insertion is textured.

It would not be obvious for one of skill in the art to combine Verdura, et al., with either Feller, Jr., et al. or McFarlane in order to achieve the device of Applicant's claim 10. The device of Verdura, et al. is limited to the surgical environment for the delivery and availability of surgical

instruments within a bodily cavity during a surgical procedure. There is no suggestion within Verdura, et al., that the device could be modified for use in an intravenous environment. Vessels such as veins and arteries are too small to receive surgical instruments as contemplated by Verdura, et al. A person of ordinary skill in the art would lack an incentive to make a combination asserted in the Office action without having knowledge of the device of Applicant's claim 10. The device recited in Applicant's claim 10 is not subject matter which would have been obvious to a person having ordinary skill in the art based on Verdura, et al., in view of Feller, Jr., et al., McFarlane, Muetterties, et al., and Steen, et al. Allowance of claim 10 is respectfully requested.

Claims 11-15 depend from claim 10. Claims 11-15 are allowable at least for the reasons set forth above with regard to claim 10. Reconsideration and allowance of claims 11-15 is respectfully requested.

Applicant further disagrees with the recitation in the Office action that claims 5-8 and 10-18 recite subject matter which are conventional enhancements well known in the art. Specifically, Applicant disagrees that Feller, Jr., et al., McFarlane, Muetterties, et al, and Steen, et al., demonstrate the conventionality of various types of textures used in surgical instruments and their application in the different external locations of stents or intravascular devices in the context of Applicant's claims 5-8 and 10-18. The textures disclosed in the cited references are positioned to facilitate the gripping and manipulation of the respective devices by the medical professional.

Applicant's texture, in sharp contrast, is positioned to assist in restricting movement of the respective stent or intravascular device within the bodily tissue at the point of insertion for the significant purpose of avoiding the introduction of infection causing organisms into the vessel by promoting tissue adhesion and fibroblast growth within the texture. The specific embodiment of the

texture in Applicant's claims 5-8 and 11-18 contemplate this purpose and are new and significant advancements in the art and not "conventional enhancements known in the art."

New Claims

New claims 19-21 have been added by way of this amendment and response. Consideration and allowance of new claims 19-21 is respectfully requested.

The Commissioner is hereby authorized to credit any overpayment or debit any additional fees which might become due during the pendency of this application to the deposit account of the undersigned, No. 06-0540.

Respectfully submitted,

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Date: February 4, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 1 has been amended as follows:

1. (Thrice Amended) An indwelling intravascular device for insertion into the bodily tissue and vessel of a medical patient, comprising:

a body including an interface and a cannula;

said cannula for extending into and terminating in the vessel;

said [a] body [including an interface] for at least partial insertion into the bodily tissue at a point of insertion;

said interface being the portion of said body which remains in contact with said bodily tissue adjacent said point of insertion while the device remains inserted in the bodily tissue;

said interface having an exterior surface including texture thereon.

Claim 10 has been amended as follows:

10. (Twice Amended) An intravenous stent for insertion into the bodily tissue of a medical patient at a point of insertion, comprising:

a stent portion;

said stent portion [capably] capable of receiving said needle therethrough;

said stent portion including an introducer and a cannula through which said needle extends;

said introducer including a proximal portion and a distal portion;

a segment of said proximal portion for contact with the bodily tissue at the point of insertion;

said introducer including texture on said segment of said proximal portion for contact with the bodily tissue at the point of insertion [proximal portion].

New claims 19-21 have been added as follows:

--19. An intravasular device for insertion and retention in a severed vessel, comprising:

a body, including an interface and a cannular;

said cannular for extending into and terminating in the severed vessel;

said interface being the portion of the body which contacts the severed vessel;

said interface having an exterior surface having texture thereon.

20. The intravasular device of claim 19 wherein the majority of said texture is between the range of 0.2 mm to 1.0 mm.

21. The intravasular device of claim 19 wherein the majority of said texture is between the range of 0.2 mm to 0.5 mm.--